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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/045,341 | 10/25/2001 | Bradley Stuart Galer | 1203-01 | 3845 |

7590

06/26/2002

IP Department
Schnader Harrison Segal & Lewis
36th Floor
1600 Market Street
Philadelphia, PA 19103

EXAMINER

OH, SIMON J

ART UNIT PAPER NUMBER

1615

DATE MAILED: 06/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/045,341 | Applicant(s) GALER, BRADLEY STUART | |
| | Examiner Simon J. Oh | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Botknecht *et al.* (U.S. Patent No. 5,885,597)

The Botknecht *et al.* patent teaches a method of relieving pain by using a topical composition comprising a local anesthetic (See Column 1, Lines 5-10; and Column 3, Line 54 to Column 4, Line 26). The method of pain relief is directed to joint disorders, such as tennis elbow, bursitis, and the various types of arthritis (See Column 1, Lines 29-48). The local anesthetic component of the composition is preferably lidocaine, including its pharmaceutically acceptable salts; the local anesthetic may be present in an amount ranging from 0.1% to 10% by weight (See Column 5, Line 46-54; and Claims 1, 8, 14 and 17).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Botknecht *et al.* in view of Higo *et al.* (U.S. Patent No. 5,866,157)

The Botknecht *et al.* patent teaches a method of relieving pain by using a topical composition comprising a local anesthetic (See Column 1, Lines 5-10; and Column 3, Line 54 to Column 4, Line 26). The method of pain relief is directed to joint disorders, such as tennis elbow, bursitis, and the various types of arthritis (See Column 1, Lines 29-48). The local anesthetic component of the composition is preferably lidocaine, including its pharmaceutically acceptable salts; the local anesthetic may be present in an amount ranging from 0.1% to 10% by weight (See Column 5, Line 46-54; and Claims 1, 8, 14 and 17).

The Botknecht *et al.* patent does not teach the use of transdermal patch in the administration of lidocaine for pain relief.

The Higo *et al.* patent teaches a patch formulation for the percutaneous absorption of a drug (See Abstract). The drug may be present in an amount ranging from 0.1% to 20% by weight of the adhesive layer, and lidocaine is listed as an example of a local anesthetic that may be used as a drug in the patch (See Column 3, Lines 31-32 and 55-63).

It would be obvious to one of ordinary skill at the time the invention was made to combine the teachings of Botknecht *et al.* and Higo *et al.* into the object of the instant application. Botknecht *et al.* teach a method for relieving pain by the topical application of lidocaine, and Higo *et al.* teach that such a topical application can be embodied in the form of a patch. One of ordinary skill would be motivated to create such an embodiment in order to avoid gastrointestinal side effects from oral administration, as well as to provide a means for the drug to be absorbed continuously, using the advancements made in the art provided by Higo *et al.*

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(See Higo *et al.*, Column 1, Lines 12-45; and Column 2, Lines 32-44). Thus, the claimed invention as a whole is *prima facie* obvious.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Patent Examiner
AU 1615.

sjoh
June 24, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNICAL CENTER 1600
